

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION

and

STATE OF NEW YORK,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC,

PHOENIXUS AG,

MARTIN SHKRELI, individually, as an
owner and former director of Phoenixus AG
and a former executive of Vyera
Pharmaceuticals, LLC,

and

KEVIN MULLEADY, individually, as an
owner and director of Phoenixus AG and a
former executive of Vyera Pharmaceuticals,
LLC,

Defendants.

Case No. 1:20-cv-00706-DLC

JOINT RULE 26(f) REPORT

Plaintiffs Federal Trade Commission (“FTC”) and the State of New York and Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, Martin Shkreli, and Kevin Mulleady, by and through their undersigned counsel, jointly submit the following Rule 26(f) Report and Discovery Plan.

The parties conducted the Rule 26(f) conference telephonically on February 27, 2020. The parties discussed all of the matters outlined in Rule 26(f) during that conference.

The parties respectfully submit the following proposed discovery plan pursuant to Rule 26(f). Where the parties were unable to agree on an issue, each side has set forth its respective position. The parties' respective proposed schedules are attached to this Report as Exhibit A.

A. Initial Disclosures – Rule 26(f)(3)(A)

The parties agree to exchange initial disclosures pursuant to Rule 26(a) no later than April 13, 2020. The parties agree that the initial disclosures will take the form prescribed in Rule 26(a), including that counsel for Defendants will identify whether any of them represents any individuals or entities identified pursuant to Rule 26(a)(1)(A)(i).

B. Subjects of Discovery and Discovery Completion – Rule 26(f)(3)(B)

1. Subjects of Discovery

Plaintiffs anticipate the subjects of discovery will include factual and expert discovery regarding the parties' respective claims and defenses, including: (1) the relevant antitrust market; (2) Defendants' Daraprim distribution agreements, agreements regarding supply of pyrimethamine active pharmaceutical ingredient ("API"), and data-blocking agreements; (3) the alleged anticompetitive and procompetitive effects, including any consumer harm, of the conduct alleged; (4) the impact of Defendants' conduct on entry into the market of generic Daraprim (pyrimethamine); (5) Shkreli and Mulleady's individual liability; and (6) the appropriate remedy.

Defendants anticipate the subjects of discovery will include factual and expert discovery regarding the parties' respective claims and defenses, including: (1) the availability of Daraprim for sale on the open market during the relevant period; (2) the likelihood and timing of generic entry for Daraprim; (3) the ability of generic manufacturers to obtain required FDA approvals and to bring a generic form of Daraprim to market; (4) the ability of API manufacturers to obtain FDA approvals and to sell pyrimethamine API; (5) the potential for recurrence of the alleged

conduct; (6) available substitutes for Daraprim and/or pyrimethamine API; and (6) defenses to Messrs. Shkreli's and Mulleady's alleged individual liability, including but not limited to the specific role and conduct of Messrs. Shkreli and Mulleady during the relevant period.

2. Fact Discovery

The parties do not agree about when fact discovery should close. The parties' respective proposed schedules are attached to this Report as Exhibit A. The parties do not agree about whether discovery should be stayed pending resolution of anticipated motions to dismiss.

Plaintiffs' Position:

Plaintiffs' position is that discovery should not be stayed pending resolution of the anticipated motions to dismiss. Plaintiffs also respectfully propose that the Court resolve this issue at the status conference scheduled for March 20, 2020. In any event, if the Court prefers full briefing on the issue, Plaintiffs do not agree with Defendants' proposal that their anticipated motion to stay should be delayed until the deadline for their motions to dismiss.

Defendants' proposed schedule contemplates a stay of discovery until this Court resolves numerous motions to dismiss that have yet to be filed. Briefing for these motions to dismiss will not be complete for about four months. Defendants provide no good cause for why the Court should diverge from "the usual practice in federal courts—permitting discovery to continue during the pendency of a motion to dismiss." *Tobias Holdings, Inc. v. Bank United Corp.*, 177 F. Supp. 2d 162, 169 (S.D.N.Y. 2001); *see also* Fed. R. Civ. P. 26(c). This well-established principle "applies with even greater force where, as here, Defendants have not yet filed a motion to dismiss, but merely contemplate one." *Noble Talents LLC v. Asch*, No. 19-cv-11020, 2020 U.S. Dist. LEXIS 25306, *1-2 (S.D.N.Y. Feb. 13, 2020).

To satisfy their "good cause" burden, Defendants must meet a three-factor balancing test

that weighs “(1) whether a defendant has made a strong showing that the plaintiff’s claim is unmeritorious, (2) the breadth of discovery and the burden of responding to it, and (3) the risk of unfair prejudice to the party opposing the stay.” *Kirschner v. J.P. Morgan Chase Bank, N.A.*, No. 17-CV-6334 (PGG) (SLC), 2020 WL 230183, at *2 (S.D.N.Y. Jan. 15, 2020) (internal quotation marks omitted). Each of the factors weighs against Defendants’ request for a discovery stay.

First, Defendants cannot make the “strong showing” that Plaintiffs’ claims are “unmeritorious.” Relying on documents and testimony from their investigation, Plaintiffs’ 65-page complaint sets forth detailed allegations that Defendants engaged in a multi-faceted anticompetitive scheme to block lower-cost generic competition to a life-saving medication in violation of federal and state antitrust laws. *See Guiffre v. Maxwell*, No. 15 Civ. 7433 (RWS), 2016 WL 254932, at *2 (S.D.N.Y. Jan. 20, 2016) (denying motion to stay because the complaint pleaded “concrete facts and law to support all of [Plaintiffs’] arguments”).

For example, the Complaint alleges that Defendants entered two exclusive contracts intended to deny generic competitors access to Daraprim’s active pharmaceutical ingredient (“API”), the key input in pharmaceutical products. Compl. ¶¶ 138-169. After securing an exclusive contract with the only supplier approved to manufacture the API for the U.S. market, Defendants then moved to sideline an API supplier that had been working with potential generic competitors. As the Complaint alleges, Defendants had no need for this second API source, and never purchased any of the API for its own product. Compl. ¶¶ 153-65. Nonetheless, Defendants paid this API supplier millions of dollars to ensure that it could not to supply its potential competitors. Compl. ¶ 60. These allegations, among many others, fully support the claims that Defendants have violated, and are continuing to violate, federal and state antitrust law. *See Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 495-501, 506-10 (2d Cir. 2004)

(finding that exclusive API contracts could form the basis for Sherman Act Sections 1 and 2 liability).

Second, Defendants cannot demonstrate that Plaintiffs’ discovery is so broad and burdensome as to merit a stay. Defendants’ position is that *any* discovery would be unduly burdensome. But instead of seeking a preemptive blanket protective order, “there is no reason that any objections to individual requests cannot be dealt with through the meet-and-confer process, and, if necessary, a conference with the Court.” *Kirschner*, 2020 WL 230183, at *3; *see also Mulligan v. Long Island Univ.*, No. 18-CV-2885 (ERK) (SJB), 2018 WL 8014320, at *3 (E.D.N.Y. Dec. 13, 2018) (denying motion to stay where defendants could “seek a protective order which the Court would consider in the ordinary course of discovery practice”). Such objections should not, however, be based solely on the pendency of the motion to dismiss.

Third, Plaintiffs—and the consumers we seek to protect—would suffer significant prejudice if the Court stayed discovery. The outcome of this case directly impacts patients, hospitals, and other organizations that would benefit from generic competition to Daraprim. Although the FDA recently approved one generic version of Daraprim, generic entry has not yet occurred. Moreover, consumers typically do not experience significant cost savings until multiple generics enter and compete. Defendants’ ongoing conduct has significantly delayed this competition. *See Guiffre*, 2016 WL 254932, at *2 (denying a stay when complaint describes an “ongoing series of events”). Plaintiffs are ready and eager to make their case at trial and to end Defendants’ anticompetitive conduct. To that end, discovery should proceed and no stay should be issued.

Defendants’ Position:

Defendants’ position is that it is inappropriate and improper for Plaintiffs to include

advocacy briefing on this issue in a Rule 26(f) Report. Moreover, it is inconsistent with the parties' discussions during their two Rule 26(f) conferences. Defendants' position is that discovery should be stayed pending resolution of the anticipated motion(s) to dismiss. Defendants plan to file a motion to stay discovery for the Court's consideration contemporaneously with their motion(s) to dismiss.

Areas of Agreement:

The parties agree that they shall serve subpoenas and discovery requests sufficiently in advance of the discovery completion date such that all responses or objections will be due on or before that date. The close of fact discovery shall not preclude requests for admission regarding the authentication and admissibility of exhibits.

Parties who produce discovery shall produce a copy of the discovery to all parties. If a non-party produces discovery to a party, the receiving party shall promptly provide a copy of the non-party discovery to all parties.

The parties agree that discovery should not be conducted in phases or limited to or focused on particular issues.

The parties anticipate that discovery of foreign entities may be necessary in this case and that it may be necessary to serve discovery pursuant to the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters or other international agreements.

3. Expert Discovery

The parties do not agree about when expert discovery should close, whether there should be reply expert reports, and whether it is appropriate to address certain expert discovery issues in this Report. The parties' respective proposed schedules are attached to this Report as Exhibit A.

Plaintiffs' Position:

The parties should be permitted to serve reply expert reports that respond to the opinions set forth in expert rebuttal reports. Reply reports would not be an opportunity to correct oversights in the original report. Instead, they would be limited to explaining, countering, or disproving the opinions of the other party. Allowing for reply expert reports will have several benefits in these proceedings. First, they will help narrow the issues of dispute among the experts, which promotes efficiency for both the parties and the Court. Second, they will ensure that all of an expert's opinions and analyses, including those that respond to points raised in opposing experts' rebuttal reports, are fairly disclosed before expert depositions. Third, given the Court's preference for written direct testimony of experts, providing for reply reports will reduce the possibility that an opposing side objects to written direct expert testimony on the ground that it contains undisclosed opinions. *See generally Ironshore Ins. Ltd. v. Western Asset Mgmt. Co.*, No. 11 Civ. 5954 (LTS) (JCF), 2013 WL 2051863, at *2 (S.D.N.Y. May 15, 2013) (Magistrate Mem. & Order) ("Reply expert reports may be appropriate if the rebuttal reports raise new matters not discussed in the initial reports.").

Plaintiffs also propose the following with respect to expert discovery. Because experts for both Plaintiffs and Defendants will likely use significant amounts of data in the preparation of their expert reports and their expert testimony, a party shall produce with any initial, rebuttal, or reply expert report, subject to any applicable protective order: (a) a list of all commercially-available computer applications used in the preparation of the report; (b) a copy of all data sets, in native file format, used or developed in the preparation of the report; (c) a copy of any customized statistical software or other customized computer programs used by the party's

expert in the course of preparing their report; (d) any processed data files developed in the preparation of the report; (e) a description of how the programs and original data set(s) were employed to create a final data set(s) if requested; and (f) a description of the purpose and format of each data file and program file with instructions on how replication can be conducted if requested.

Defendants' Position:

Defendants' position is that the parties should not be permitted to serve reply expert reports as these are neither necessary nor customary. In addition, Defendants' position is that Plaintiffs' proposed schedule for the timing of expert reports in Exhibit A is unrealistic, unreasonable and plainly designed to unfairly advantage Plaintiffs; Plaintiffs propose two months for Plaintiffs' expert reports, only one month for Defendants' rebuttal reports, fourteen days for reply reports, but only thirty days for expert depositions. This is in contrast to Defendants' more reasonable proposed schedule that eliminates expert reply reports and instead gives the same amount of time for Plaintiffs' and Defendants' expert reports -- two months for each of Plaintiffs' expert reports, and for Defendants' rebuttal reports -- and then two months for expert depositions. Further, Defendants' position is that any specifics regarding expert discovery are premature and inappropriate for a Rule 26(f) Report; rather, these would be better served as part of an expert discovery protocol that the parties could negotiate at a more appropriate time in the future.

C. Disclosure, Discovery, or Preservation of ESI – Rule 26(f)(3)(C)

The parties anticipate that the scope of discovery will encompass Electronically Stored Information ("ESI"). The parties will request ESI in the form or forms that facilitate efficient review of ESI. In general, the parties will produce ESI either according to the same ESI technical

specifications used by Defendants in the FTC's pre-complaint investigation or in accordance with an ESI protocol as agreed among the parties or ordered by the Court.

The parties disagree about whether certain potential issues relating to ESI need be presented in this Report.

Plaintiffs' Position:

Plaintiffs have raised several issues regarding the preservation, collection, and production of ESI and other relevant discovery materials from the personal files and email accounts of Defendants Shkreli and Mulleady and the employees of Defendants Vyera and Phoenixus. The parties are continuing to negotiate and discuss these issues, and Plaintiffs may raise with the Court unresolved issues (if any) requiring the Court's attention.

Defendants' Position:

Defendants' position is that there is no issue with regard to preservation. Plaintiffs have not identified any specific issues or non-compliance with ESI preservation and conceded as much on the Rule 26(f) teleconference on February 27, 2020. All Defendants understand their ESI preservation obligations and made this known to Plaintiffs during that Rule 26(f) teleconference. Thus, Defendants' position is that there is no need to have a provision regarding the preservation of ESI in this Report.

D. Privilege – Rule 26(f)(3)(D)

The parties agree to the following guidelines concerning the preparation of privilege logs: identification of the litigation or potential litigation underlying attorney work product claims is permitted; identification of the name and the company for each non-Defendant person is sufficient identification; and there is no requirement to identify the discovery request to which each privileged document was responsive.

The parties agree that the following privileged or otherwise protected communications may be excluded from privilege logs:

- (a) any documents or communications sent solely among outside counsel for the Defendants or persons employed or retained by such counsel;
- (b) after the filing of the Complaint for Injunctive and Other Equitable Relief on January 27, 2020, any documents or communication regarding the conduct of this litigation sent solely among outside counsel for the Defendants or sent solely between outside counsel for the Defendants and (i) Defendants or (ii) Defendants' employees. Notwithstanding the foregoing, privileged documents or communications that may otherwise be exempt from logging under this subpart must nevertheless be logged if any portion of the document or communication also concerns ongoing or forward-looking business decisions, plans, actions, or practices.
- (c) any documents or communications sent solely among counsel for the Plaintiffs or persons employed or retained by the Plaintiffs for the purpose of this litigation or the pre-Complaint investigations; and
- (d) non-responsive privileged documents attached to responsive documents; however, when privileged documents that are attached to responsive documents are withheld from production, the parties will insert a placeholder to indicate a document has been withheld from that family; and
- (e) draft litigation filings.

The parties agree that, to the extent Defendants served privilege logs on the Plaintiffs during the pre-Complaint investigations, those privilege logs are deemed served in this action. The parties agree to produce documents in this matter on a rolling basis and serve privilege logs no later than 45 days after each production, unless otherwise agreed. The parties further agree

that they have reserved all rights to challenge any privilege claims, whether described on logs previously produced or otherwise.

E. Limitations on Discovery – Rule 26(f)(3)(E)

The parties disagree about the allocation of time during non-party depositions.

Plaintiffs' Position:

During non-party depositions, if both sides cross-notice the deposition, then the time will be divided equally, *i.e.*, three and one-half hours for each side. Any time allotted to one side not used by that side may be used by the other side up to the seven-hour limit in total. The parties may, by mutual consent, agree to a different allocation of time for specific non-party depositions without leave of Court. Current and former employees of the Defendants do not count as non-parties for purposes of this proposal.

Plaintiffs' proposal to allocate time at non-party depositions equally between the parties is practical, fair, and reduces the likelihood that the Court will be dragged into disagreements about the proper allocation for particular depositions. The proposal also is flexible. By setting only a default rule, it allows the parties to negotiate changes in the time allocation where appropriate. Finally, allowing one side to use the other's unused time should limit any gamesmanship with cross-noticing of depositions. Defendants' proposal to rely on the Federal Rules of Civil Procedure is ineffective because the Rules do not address how to allocate time between the parties for non-party depositions. Thus, Defendants' proposal is likely to lead to disagreements that ultimately will need to be resolved by this Court.

Defendants' Position:

Defendants' position is that the Federal Rules of Civil Procedure governing depositions, including Fed. R. Civ. P. 30(d)(1), will apply, unless the parties agree to particular modifications,

which would be addressed on a deposition-by-deposition basis. Plaintiffs' proposal is unnecessary and could lead to gamesmanship with cross notices and time allocations being taken up strategically, especially since most of the non-parties have presumably already spoken to the Plaintiffs, whereas Defendants have had access to none of them. Moreover, Plaintiffs' unwillingness to apply their protocol to former employees of the Companies, meaning that the presumption would not apply to those individuals, substantially undermines Plaintiffs' position and supposed rationale.

Areas of Agreement:

The parties agree that there shall be no limitations on the number of requests for the production of documents pursuant to Rule 34 or on the number of requests for admission pursuant to Rule 36. Each party reserves the right to seek a protective order pursuant to Rule 26(c) with respect to specific discovery requests.

The parties agree that each side shall serve no more than twenty-five interrogatories, including all discrete subparts.

The parties agree that it will be necessary to take more than ten depositions as permitted under Rule 30(a)(2)(A).

The parties propose that the limitation on depositions be increased to 200 hours per side for fact depositions.

The parties agree that testimony taken in investigational hearings during the FTC's pre-Complaint investigation do not count towards the number of hours agreed above. Either party may further depose witnesses whose testimony was taken in investigational hearings during the pre-Complaint investigations. The parties also agree that expert depositions shall not count towards the number of hours allotted for depositions.

F. Other Orders That the Court Should Issue – Rule 26(f)(3)(F)

The parties are negotiating a stipulated protective order that they intend to present to the Court. The parties agree that neither side should exchange documents under Rule 26(a)(1)(A)(ii) until a protective order is entered in this case. The parties agree that they will negotiate an expert protocol that will address discovery of expert materials.

G. Other Matters

1. Settlement

The parties discussed settlement during the Rule 26(f) conference, and it does not appear that settlement is likely at this time.

2. Witness Lists

The parties disagree about the procedure for finalizing witness lists and whether there should be opportunity to depose previously unidentified witnesses.

Plaintiffs' Position:

A party's final witness list may include individuals not previously identified on (i) the Rule 26(a) initial disclosures or (ii) Rule 26(e) supplemental disclosures that have been provided at least 30 days before the end of fact discovery, so long as the opposing parties are provided a reasonable opportunity to take the witness's deposition before the pretrial conference. The limitation on depositions shall not include depositions of any person identified in the final trial witness list who was not previously disclosed in (i) or (ii) above and was not previously deposed.

Plaintiffs' proposed rule is consistent with a "basic purpose" of the Federal Rules of Civil Procedure to facilitate the full disclosure of relevant information during discovery and to prevent "trial by ambush." *In re Hornbeam Corp.*, No. 14 Misc. 424 (Part 1), 2015 WL 13647606, at *5 (S.D.N.Y. Sept. 17, 2015) (quoting *Ginns v. Towle*, 361 F.2d 798, 801 (2d Cir. 1966)). Rule

26(a)(1)(A) requires a litigant to identify each individual likely to have discoverable information that the disclosing party may use to support its claims or defenses in its initial disclosures, and Rule 26(e) imposes a continuing duty to supplement such disclosures in a timely manner throughout the discovery period if the litigant learns they are incomplete or incorrect in any material respect. By ensuring that the opposing parties will have the opportunity to depose a late-identified witness, Plaintiffs' proposal both discourages gamesmanship by eliminating any unfair advantage to be gained and provides for fair and orderly discovery by the opposing parties when a witness is identified late.

Defendants' Position:

Defendants' position is that specifics regarding witness lists for trial are premature and improper for a Rule 26(f) Report.

3. Consent to Magistrate Judge

The parties do not consent to proceed before a magistrate judge.

4. Joinder of Parties and Amendment of Pleadings

Plaintiffs anticipate that additional states may join as Plaintiffs in this action. The parties propose June 19, 2020 as the final date by which parties may be joined. Plaintiffs reserve all of their rights to seek leave to amend the Complaint.

5. Service of Pleadings and Discovery

The parties agree that service of all pleadings and discovery, including copies of Rule 45 subpoenas, and delivery of all correspondence in this matter shall be made by email or FTP to counsel of record for each party, except when the volume of attachments requires overnight delivery of the attachments or personal delivery, in which case service shall be made to the following individuals designated by the parties for each side noted below:

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Each side shall copy and produce materials obtained in discovery, in the format they were received from any non-party, to the other parties, within three business days after receipt by the side initiating the discovery request; except that if a non-party produces materials that are not Bates-stamped, the party receiving the materials may Bates-stamp them before producing a copy to the other parties and shall produce the documents or electronically stored information in a reasonable time.

Dated: March 12, 2020

Respectfully submitted,

/s/ Markus H. Meier
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EXHIBIT A
PROPOSED SCHEDULE

Event	Plaintiffs' Proposed Deadline	Defendants' Proposed Deadline
Initial Disclosures Served	April 13, 2020	April 13, 2020
Initial Pretrial Conference	March 20, 2020	March 20, 2020
Defendants' Motion to Stay Discovery	Not applicable (The parties' statements in this Report suffice)	May 22, 2020
Plaintiffs' Opposition to Motion to Stay Discovery	Not applicable	July 6, 2020
Defendants' Reply in Support of Motion to Stay Discovery	Not applicable	July 27, 2020
Defendants' Motion(s) to Dismiss or Answers	May 8, 2020	May 22, 2020
Plaintiffs' Opposition(s) to Motion(s) to Dismiss	June 22, 2020 (+45 days)	July 6, 2020
Defendants' Reply(ies) in Support of Motion(s) to Dismiss	July 13, 2020 (+21 days)	July 27, 2020
Deadline for Joining Additional Parties or Amending Pleadings	June 19, 2020	June 19, 2020
Close of Fact Discovery	December 18, 2020 (nine months)	18 months after the resolution of motions to dismiss
Expert Reports from Parties Bearing the Burden on an Issue	February 16, 2021 (+60 days)	2 months after the close of fact discovery
Rebuttal Expert Reports	March 18, 2021 (+30 days)	4 months after the close of fact discovery
Reply Expert Reports	April 1, 2021 (+14 days)	Not applicable
Close of Expert Discovery	April 30, 2021 (+30 days)	6 months after the close of fact discovery
Motion(s) for Summary Judgment	June 14, 2021 (+45 days)	[TBD]
Opposition(s) to Motion(s) for Summary Judgment	July 29, 2021 (+45 days)	[TBD]
Reply(ies) in Support of Motion(s) for Summary Judgment	August 19, 2021 (+21 days)	[TBD]
If no Summary Judgment Motions filed, Joint Pretrial Motion	June 30, 2021	[TBD]

CERTIFICATE OF SERVICE

I hereby certify that on March 12, 2020, I served a true and correct copy of the foregoing document and exhibits on all counsel of record via the Court's CM/ECF system.

Dated: March 12, 2020

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